Lost in Menuspace: User Interactions With Complex Medical Devices

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***Abstract*—The advent of fast-acting drugs has made the infusion pump the most pervasive electronic medical device in the acute care (hospital) environment. Despite the importance of its correct operation, incident reports in the US Food and Drug Administration (FDA) database implicate interface programming as a significant aspect of adverse outcomes. This article describes a study of infusion pump-programming performance by experienced healthcare professionals in a major urban teaching hospital. Early findings indicate that practitioner experience with device programming does not increase proficiency. This suggests that a complex menu structure ("menuspace") makes programming difficult and inefficient in ways that impede practitioner development of mental models that are sufficient for reliable device operation. This causes operators to become disoriented in the interface structure, or "lost in menuspace." We relate these findings to the current study of the USFDA adverse events reports and indicate directions for further research.**

***Index Terms*—Heathcare, human factors, human–machine interaction, infusion device, safety.**

I. Introduction

POTENT, short-acting intravenous medications form an important part of critical care. Previously, the use of fixed long-acting drugs, such as intramuscular morphine injections limited intravenous medication to comparatively benign fluids such as saline. The drug's effect on the patient was gradual and minor variations in dosing rates could be tolerated. Current medical practice makes use of a larger number of pharmaceutical agents. Moreover, newer agents are more potent and faster in onset/offset of action than their predecessors. Some, such as chemotherapeutics for cancer, require complex, changing infusion schedules. Deliberate administration to body compartments other than the blood, such as the spinal fluid, further complicates infusion practice. The pharmacology of these agents, as well as different practice patterns, has driven the need for multiple carefully controlled infusion schemes. Electronic infusion pumps have been developed to manage the administration of these medication schemes. However, programming these devices has presented unforeseen complications that present significant implications for medical safety.

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A. Infusion Devices

Historically, care providers rigged a bag of medication that relied on gravity to draw the fluid through flexible tubing to the patient. Droplets of the fluid could be seen to form and drip into the tubing. This "drip" was regulated by a simple manual fluid flow resistor placed in series with the infusion tubing. Practitioners observed the droplet formation rate and adjusted the resistor to achieve the proper dosing scheme.

The advent and proliferation of potent, short-acting intravenous agents for use in anesthesiology and critical care medicine required precision and accuracy and the perception was that the simple control loop of a gravity-fed drip could not provide it. The advent of small, cheap microprocessors led to the development of infusion pump systems that were capable of performing consistently and with high accuracy. Most infusions in US hospitals are now provided by such devices [1]. Fig. 1 compares manual and semiautomated approaches to infusion. In the manual arrangement, a clinician observes fluid drip directly and controls its rate using a mechanical resistor. In the semiautomated arrangement, the clinician observes the display that reports on microprocessor status and presses controls to change the microprocessor state. The microprocessor controls and monitors the pump mechanism, which, in turn, moderates fluid flow to the patient.

Electronic devices make it possible to precisely deliver fixed volumes of medications (fluid bolus), continue medication delivery while unattended, administer infusions of short-acting drugs at a constant rate, and titrate particular kinds of medications to desired effect (such as vasopressors, which are used to control blood pressure). Infusion devices now provide clinicians with aids to calculate medication doses. In some instances, one pump is used for each intravenous medication. Newer multichannel pump designs infuse more than one medication at a time. More than ten pumps have been seen used at the same time to provide medications and fluids for a single intensive care unit (ICU) patient. US Food and Drug Administration (FDA) classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Infusion pumps are a USFDA Class II device, which are subject to special controls, such as mandatory performance standards.

Manufacturers typically represent their infusion pump product as precise, accurate, reliable, and flexible. Pumps are described as being able to automate multistage processes such as piggybacks and step infusions, to compensate for the staff's limited abilities to pay attention, calculate doses, and adjust medications.

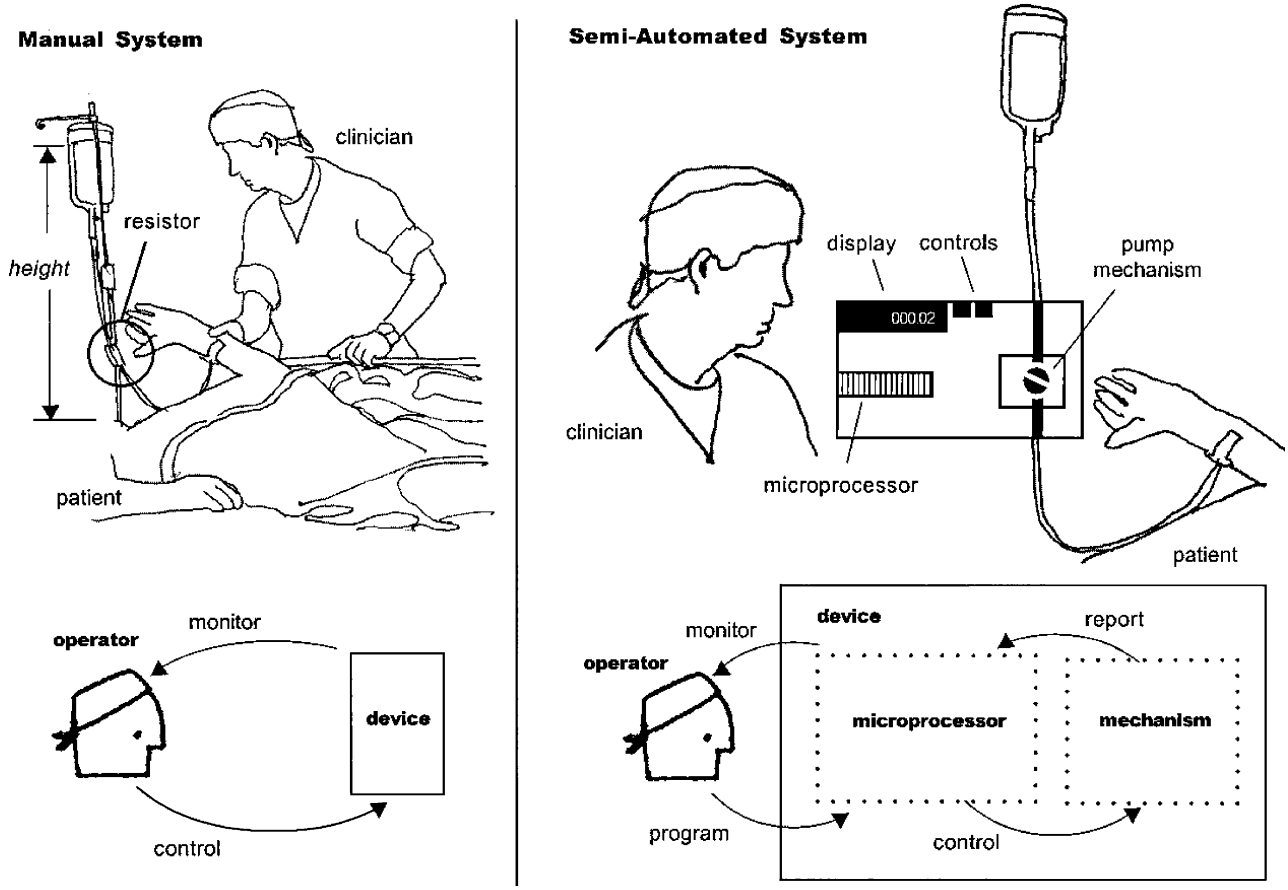

Fig. 1. Infusion device as a manual and semiautomatic system.

B. Adverse Incident Reports

In spite of technological progress in the practice of infusions, failures and adverse events are plentiful. Cook *et al.* [2] and Cook and Woods [3] provide examples of drug infusion adverse incidents involving these devices. Attempts have been made to create adverse event-reporting systems in order to capture and analyze incidents and accidents. Reporting incidents that involve healthcare devices is mandatory and the USFDA Center for Devices and Radiological Health (CDRH) Manufacturer and User Device Experience (MAUDE) database[1] serves as a report clearinghouse. MAUDE database entries show that problems with infusion devices are common although submissions to the MAUDE database are often incomplete. Entries frequently lack deeper explanations of the circumstances in which adverse events occur and fail to identify specific causes. Instead of causes, events that involve infusion devices often attribute the outcome to "user error" [4].

In a study of the affect of information technology on healthcare practice,[2] we sought to answer three questions: How is the programming of a specific infusion pump structured? How do the users accomplish programming tasks within this structure? How do existing incident reports help to describe adverse events in terms of infusion device programming characteristics?

[1]http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM.

[2]Clinical Informatics to Promote Patient Safety (CLIPS).

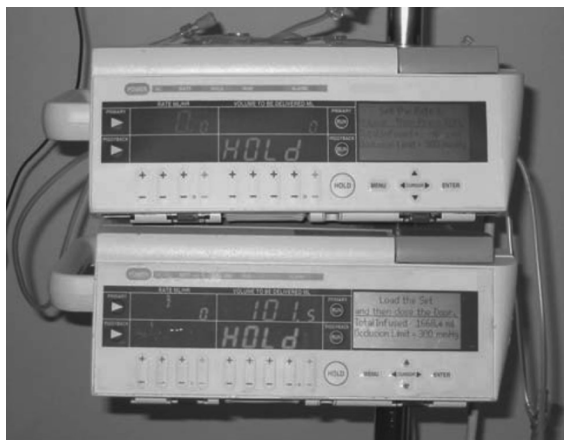

Fig. 2. Experiment apparatus: two infusion devices.

II. Methods

The first phase in the study sought to understand all of the possible routes that subjects could take while programming a pump. Lab staff systematically programmed one type of infusion pump, shown in Fig. 2, to explore all possible programming permutations. This pump allows multiple pathways to enter the data that is needed to begin an infusion and provides multiple modes for infusion. Pump programming structure, or "menuspace," was then represented as a state diagram that depicted all possible programming routes. The state diagram was used during later observation and analysis, making it possible to trace

TABLE I
PUMP STUDY SAMPLE EXPERIENCE AND PERFORMANCE

Data

Anesthesiologists

Subj	Exper (pract)	Exper (pump)	%GDK Task 1	%GDK Task 2	%GDK Task 3	%GDK Task 4	Mean %GDK
2	3	3	25	71.4	41.5	81.8	54.925
3	2	2	33.3	100	69.2	93.3	73.95
4	3	3	53.6	71.4	91.2	88.9	76.275
5	4	4	40	100	86.5	93.3	79.95
6	3	3	46.5	73.3	90.6	97	76.85
7	1	1	39.1	66.7	94.7	41.3	60.45
8	3	3	55.6	93.8	100	83.1	83.125
9	3	3	40	100	100	96.3	84.075
10	11	5	35.3	72.7	92.9	74.4	68.825
11	3	3	72.7	90 32.6	90.3		71.4
12	4	4	25	100	90	88.9	75.975
13	5	5	100	87.5	90	100	94.375
14	12	5	61.5	83.3	81.8	88.6	78.8
15	14	5	7.6	100	100	69.1	69.175
mean	5.07	3.5					

ICU Nurses

Subj	Exper (pract)	Exper (pump)	%GDK Task 1	%GDK Task 2	%GDK Task 3	%GDK Task 4	Mean %GDK
16	5	5	95.45	85.71	85.71	91.11	89.495
17	13	5	100	85.71	75	100	90.1775
18	13	4	100	66.66	100	68.42	83.77
19	2.5	0.92	100	85.71	75	100	90.1775
20	4	1.5	100	88.88	57.14	95.83	85.4625
21	5	2	100	85.71	100	83.33	92.26
22	6.5	3	90.9	100	92.3	97.05	95.0625
23	10	3	73.68	83.33	61.53	94.11	78.1625
24	20	5	80	85.71	95.23	100	90.235
25	7	5	30.76	83.33	97.36	90.9	87.115
26	14	5	71.42	100	100	81.48	88.225
27	2.5	1	100	85.71	52.94	80.55	79.8
28	18	5	60	87.5	100	100	86.875
29	22	5	100	100	35	100	83.75
30	8	2	88.88	100	31.53	93.33	78.435
31	1.5	1.5	71.42	85.71	86.66	95.65	84.86
32	3	1.5	100	87.5	100	84.84	93.085
33	26	2	83.33	75	85.71	103.12	86.79
34	30	5	100	100	90	100	97.5
35	2.5	2	100	85.71	36.76	87.5	77.4925
36	5	1	61.53	75	76.47	86.11	74.7775
37	20	5	0	80 50	100		57.5
38	22	5	20	83.33	81.25	96.55	70.2825
39	25	5	93.33	90.9	17.5	100	75.4325
40	25	5	90.9	66.66	100	100	89.39
41	12	2	84.61	90.9	45.2	96.55	79.315
mean	12.40	3.36					
Group mean	9.78	3.41					80.878

Correlations (Pearson *r*)

Anesthesiologists

Exper (practitioner) vs. Mean %GDK
-0.001177468

Exper (pump) vs. Mean %GDK
0.377244483

ICU Nurses

Exper (practitioner) vs. Mean %GDK
-0.085165586

Exper (pump) vs.Mean %GDK
-0.006092149

Group

Exper (practitioner) vs. Mean %GDK
0.138680228

Exper (pump) vs.Mean %GDK
0.077224274

each subject's route through the interface architecture. It also enabled the team to determine the minimum number of keystrokes that were required to reach the desired state for each task [5], [6]. The second phase was a laboratory experiment in which subjects operated the pump. In the third phase, field observations were performed to validate lab results. A fourth phase reviewed the MAUDE database for all adverse event reports related to the infusion pumps under study.

Table I describes a sample of 14 anesthesiologists (January 2002) and 26 ICU nurses (August 2003) from the same research site who were invited to participate in individual programming sessions. All sample members had significant experience with this pump, ranging from 11 months to five years. Using verbal protocol analysis (VPA), the subjects were asked to speak their thoughts aloud while they performed four pump programming tasks shown in Table II on the apparatus shown in Fig. 2. Tasks

TABLE II
INFUSION DEVICE PROGRAMMING TASKS

Task	Activity
1	Check a running dose of the drug dopamine (a premix concentration of 400milligrams in 250milliliters) that is set to run at 3micrograms/kilogram/minute for a 75 kilogram patient.
2	Change the same dopamine infusion to a rate of 2micrograms/kilogram/minute.
3	Set up and run a second powered down pump to deliver 1liter of intravenous fluid over 8hours.
4	Change the pump from scenario 3 to now deliver dopamine (400milligrams/250milliliters) at 3micrograms/kilogram/minute in a 65kilogram patient.
5	Change the same pump to deliver a premix of the drug nesiritide at a rate of 1microgram/kilogram/minute (a higher than normal dose).

ranged from simple to slightly more complex and were similar to subject experiences in their daily work:

1) check a running dose of the drug dopamine (a premix concentration of 400 mg in 250 ml) that is set to run at 3 mcg/kg/min for a 75-kg patient;
2) change the same dopamine infusion to a rate of 2 mcg/kg/min;
3) set up and run a second pump (powered down) to deliver 1 l of intravenous fluid over 8 h;
4) change the pump from scenario 3 to now deliver dopamine (400 mg/250 ml) at 3 mcg/kg/min in a 65-kg patient; a fifth question was added to the nurse sample test and later used for qualitative analysis;
5) change the same pump to deliver a premix of the drug nesiritide at a rate of 1 mcg/kg/min (a higher than normal dose).

Unlike dopamine, nesiritide and its stock concentrations are not in the software drug library of the pumps. This required the user to abandon library-based programming and enter all of the data manually.

Sessions were recorded on audio- and videotape, and the videotapes were analyzed to the level of individual keystrokes. These analyses were compared to the state diagrams of the device menu structure. User programming was analyzed for efficiency, choice of mode, and sequence selection [7].

III. RESULTS

Any keystrokes that moved the program sequence in the direction of the goal state were coded as goal-directed keystrokes (GDK). A comparison between the minimum number of possible keystrokes for the task (from the state diagram) with the total number of keystrokes that the subject actually entered indicated programming efficiency. Subjects who knew "where to go" while programming the device would have a greater percentage of keystrokes that were goal-directed.

Successful programming performance has clinical consequences. Comparing members of the sample with averages for the sample gives a fair assessment of subject performance. Finding central tendencies of subject performance is less revealing than understanding how subjects varied in the way they programmed pumps. In particular, we examined the correlation between experience and performance [8]. Our analyses provided the basis for findings that are related to infusion device controls and displays, as well as the semantic structure of infusion device user interface control software.

A. Control and Display

The limited number of keys gives the controls for this particular pump a simple appearance. This simplicity, though, requires that keys have several different functions, depending on device state. These functions are not necessarily obvious during programming and it is not apparent which keys are active at any given point in time. Screen and cursor manipulations linked to functions create the possibility for inadvertent changes to the device program. The pump operator moves a highlight cursor over various options on an LCD screen in order to perform programming steps. Options could be chosen or changed when highlighted, although other options that were available were often not displayed. Extra key presses offer the increased opportunity for inadvertent program operation. Although no subject in our study performed an inadvertent operation that altered the final results of the infusion scheme, there were several instances of operations that occurred without the knowledge of the user. Additionally, screens can be changed by certain commands. There are only ten keys available to power up/down, run, program, and input selections. An additional 11 keys are available to enter numerical data. As a result, many keys have several possible functions. Not all keys are active in all states. Any of those functions might be available, depending on the device state. It is sometimes apparent which keys are operational by text on the screen. The caption "Press HOLD: to Start Over" is one example. At other times, there is no indication which keys are active and which keys are not. Several manipulations of the screens or highlight cursor are linked to functions. Movement of the cursor in a dose calculation screen changes the relationship between dependent and independent variables in dose calculations. Data

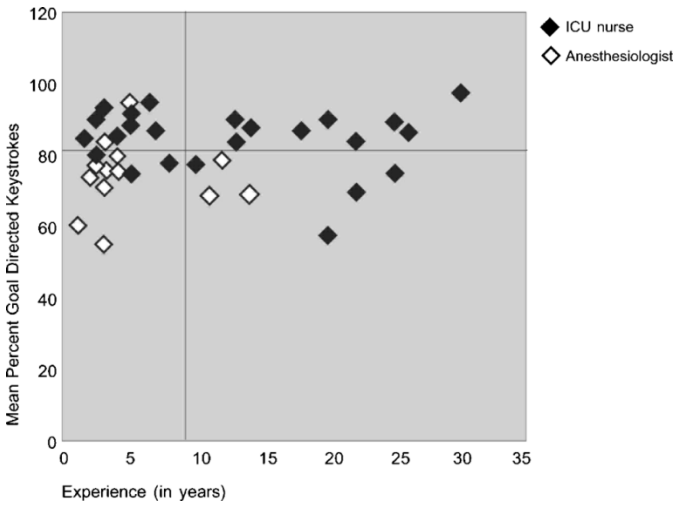

Fig. 3. Mean percent goal-directed keystrokes versus years of experience as a practitioner.

must be accepted into the device's storage in order to leave certain screens and access others.

B. Interface Design

Table I shows each subject's years of experience as a healthcare practitioner ("pract"), and with operating the pump in this study ("pump"). It shows percent goal-directed keystrokes (%GDK) for each subject and the mean %GDK for all four tasks. It then gives the correlation between years of experience as a practitioner (as an anesthesiologist or nurse) and years of experience operating this pump sorted by anesthesiologist, ICU nurse, and the entire sample. None of the correlations reached a level of significance. Fig. 3 illustrates the correlation (Pearson r: 0.1386) of sample member experience in years with the mean percentage of goal-directed keystrokes that each subject used in order to accomplish all of the four tasks. The very low correlation indicates that even as practitioner experience increases their ability to use the pump does not improve.

State diagram analysis showed that the 40 subjects could accomplish Tasks 1–4 using a minimum number of 1626 keystrokes. Sample members used 3796 total keystrokes. Of those, 2640 (69.5%) were goal-directed. Comparison between total and minimum keystrokes shows that subjects entered 57.1% more keystrokes than were necessary to accomplish the tasks.

The complexity of menuspace makes operations within it difficult. We believe that the inefficiencies seen in our subjects represent the difficulties that are involved in navigating a vast number of programming pathways. Behaviors such as power-downs (an occasion in which individual turns electrical power off to clear the interface buffer and restart programming) suggest that subjects frequently encounter fruitless pathways and must exit from them in order to finish a successful programming sequence. Our subjects were usually able to successfully complete the tasks given to them, but frequently took circuitous routes to do it.

IV. Discussion

Subjects were presented with slightly different default system states and therefore had different starting points for a task depending on the system state at the end of the previous programming task. This makes it difficult to identify a keystroke as an "error." In addition, a subject could arrive at the correct system state using any number of approaches. Understanding performance in programming an infusion pump has more to do with whether the subject reached the correct state and the route that was taken to get there, rather than how many right or wrong keystrokes were entered. It would be unfair to compare subjects solely on the basis of time to complete programming task or total keystrokes because some were offered pumps in default state that varied. Some subjects began their task with a pump state that was very close to the desired state while others were quite far away. As a result, variation in total keystrokes had little to do with user performance.

The conclusions that can be drawn from this study cover the methods that were used to understand these complex devices, what has been learned about pumps and their programming, what implications this may have for adverse event reporting, and what further work might shed light on the topic.

Scoring individual keystrokes required a substantial working knowledge of capabilities and restrictions in the various programming pathways. As a method that is proven to assist the analysis of other complex systems [5], finite state diagrams permitted us to fully describe the inner workings of the infusion device before lab and field studies. Creating diagrams of the pump menu structure revealed modes and states, as well as device features that were enabled at each step in a programming pathway. Without such maps, it would have been difficult to impossible to know how subjects got lost or found their way back to a desired goal state. The data in this study do not support definitive conclusions regarding pump operation, which is in itself revealing. There must be some other issues at play that have not yet been discovered. Findings among the 40-member sample (including ICU nurses) confirm initial observations about programming performance that concluded infusion device complexity lies hidden beneath layered, nested menus with irregular branching [9]. The complexity of the menu structure, the *menuspace* of the device, appears to defy any attempts at mastery. Even the most skilled users appeared to have a working knowledge of a small portion of the pathways. That made becoming "lost" very likely. This suggests that there are deep difficulties with the interface.

No operator failed to reach the correct goal state in each of this experiment's four assigned tasks. Yet none of the factors tells us that there is one group or individual that can use the device well. How *do* operators know how to make the device work? Subject comments from this first sample indicate that flow rate (ml/min) appears to be one variable on which operators rely. Operators also appear to develop personal strategies to reach desired goal states. These strategies may work in the lab but are vulnerable to other influences when operating pumps in actual conditions.

These initial findings give us the opportunity to better understand actual adverse events that are associated with infusion

devices as reported to the USFDA's MAUDE database. Even though we have previously described how these databases lack sufficient detail from which to draw reliable conclusions [4], it is possible to produce plausible scenarios to describe the occurrences of the events. In actual use, operators do not have the convenience of unlimited time to probe various paths to find the correct route as they did in the lab study reported here. It is possible that practitioners who are involved in adverse events that are reported in the MAUDE database have employed personal programming strategies and thought that they had reached the goal state but were prevented from verifying it by intervening events.

V. Further Work

Further research is now underway to determine whether practitioners get lost in other programming activity. This includes:

1) the study of other pump brands and types (such as syringe pumps);
2) the collection of performance data on additional tasks including a more complex patient scenario, more complex dosing, intervening or emergent condition, and marginally detectable degradation in patient condition ("going sour");
3) the observation of pump use under actual conditions

VI. Summary

Our study represents a new approach to looking at infusion pump safety in terms of usability and human/device interaction.

We believe the methods that we described provide a useful basis to study the evolution of adverse events. Lab studies show actual programming activity that is accurate at the keystroke-level. Field observation reveals actual issues in programming as well as physical configuration. Both enable the researcher to gain insight into the context of adverse events that are reported in the MAUDE database.

Those who develop and manufacture infusion pumps will receive the greatest benefit from this research. Through it, the Lab seeks to encourage the design of products that have more apparent ("transparent") functions and provide better feedback on the actual state of the device. These improvements will help to diminish the current ambiguity in pump operation. They will also improve the compatibility between infusion pumps and anesthesia work requirements.

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